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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,969	08/04/2003	Satishchandra P. Patel	M0025.0294/P0294	4463

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EXAMINER	
HAMIDINIA, SHAWN A	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,969	PATEL, SATISHCHANDRA P.	
	Examiner	Art Unit	
	Shawn Hamidinia	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is not necessary.

Priority

2. The current application filed on August 4, 2003 claims benefit of United Kingdom application 0218003.2 filed on August 2, 2002.

Information Disclosure Statement

3. The information disclosure statements filed on August 1, 2003 and August 4, 2003 have been considered. Please see the attached initialed PTO-1449s.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "and the co-carrier is 30 to 40% by weight" in line 4. There is insufficient antecedent basis for this limitation in the claim as it appears to claim from claim 7. However there is no mention of "co-carrier" in claim 7.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-22, are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US 6,248,363).

Patel et al. teach pharmaceutical delivery systems for pharmaceutical active ingredients for improved delivery of the active ingredients, (see lines 5-37, column 1). The most preferred hydrophobic active ingredients include cyclosporine (see lines 31-34, column 7), wherein the cyclosporine represents approximately 4.6 to 50 % by weight of the solid carrier (claim 57). Patel et al. describes in one embodiment that the pharmaceutical composition includes a solid carrier, a non-ionic surfactant, and other surfactants including glycerol monooleate, sorbitan monolaurate, sorbitan monooleate (see Tables 5, 9 and 11). Patel et al. teach that the HLB values of the non-ionic surfactants have an HLB level greater than 10 (see columns 11-12; Table 5, column 17; claim 41). Patel et al. further teach that the preferred non-ionic surfactants include

polyoxyethylene sorbitan fatty acid esters (see lines 30-42, column 32), PEG-40 hydrogenated castor oil, PEG-50 hydrogenated castor oil, PEG-60 hydrogenated castor oil (see Table 5, column 17), polyoxyethylene hydrogenated vegetable oils, polyoxyethylene sorbitan (see lines 45-67, column 30), and surfactants that are reaction mixtures of polyols (glycerol, sorbitol) and fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils or sterols (see lines 1-11, column 31). Patel et al. teach that the pharmaceutical composition contain the coating excipients dibutyl phthalate and phthalate esters (see lines 41-46, column 40; lines 14-26, column 44), wherein this additive is 10-25% by weight. Patel et al. also teach a pharmaceutical composition which further comprises antioxidants such as BHT, BHA, and tocopherol (see lines 26-30, column 39). Patel et al. describe that the pharmaceutical composition can be formulated as a minicapsule, capsule, a temporary or permanent suspension for oral delivery (see lines 38-54). Patel et al. describes that when formulated as a capsule, the capsule can be a hard or soft gelatin capsule, (see lines 13-16, column 42).

A person of ordinary skill in the art at the time the invention was made would have been motivated to substitute a cyclosporine agent with cyclosporin because it is the same pharmaceutical active agent which has the same function and purpose.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the pharmaceutical delivery system including a solid carrier, non-ionic surfactant, plasticizers, and antioxidants formulated as a capsule or suspension to gain the advantages of improved bioavailability for cyclosporine, increased chemical storage stability, and decreased biovariability of the active

ingredient as taught by Patel et al. (see columns 1 and 2) with the further advantage of improved palatability and/or masking the taste of a pharmaceutical active ingredient (see lines 27-31, column 53).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawn Hamidinia whose telephone number is (571) 272-4534. The examiner can normally be reached on Mon-Fri from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAH

ROBERT A. WAX
PRIMARY EXAMINER